



PTO/SB/08a (05-07)

Approved for use through 09/30/2007. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number	09955801
Filing Date	2001-09-19
First Named Inventor	Taneja, Rajneesh
Art Unit	1615
Examiner Name	SHEIKH, HUMERA N
Attorney Docket Number	065478-0159

U.S. PATENTS

Examiner Initial*	Cite No	Patent Number	Kind Code ¹	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear
	1	4554276		2007-10-17	LaMattina	
	2	4676984		1987-06-30	Wu et al.	
	3	4757060		1988-07-12	Lukacsko et al.	
	4	4766117		1988-08-23	Crawford et al.	
	5	4853230		1988-11-22	Lovgren et al.	
	6	5037815		1991-08-06	Lukacsko et al.	
	7	5071643		1991-12-10	Yu et al.	
	8	5204118		1993-04-20	Goldman et al.	

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number		09955801
Filing Date		2001-09-19
First Named Inventor	Taneja, Rajneesh	
Art Unit	1615	
Examiner Name	SHEIKH, HUMERA N	
Attorney Docket Number	065478-0159	

	9	5417980		1995-05-23	Goldman et al.	
	10	5629013		1997-05-13	Upson et al.	
	11	5753265		1998-05-19	Bergstrand et al.	
	12	5763422		1998-06-09	Lichtenberger et al.	
	13	5817338		1998-10-06	Bergstrand et al.	
	14	5955451		1999-09-21	Lichtenberger et al.	
	15	5972389		1999-10-26	Shell et al.	
	16	6015801		2000-01-18	Daifotis et al.	
	17	6024222		2000-02-15	Friberg et al.	
	18	6090827		2000-07-18	Erickson et al.	
	19	6160020		2000-12-12	Ohannesian et al.	

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number	09955801
Filing Date	2001-09-19
First Named Inventor	Taneja, Rajneesh
Art Unit	1615
Examiner Name	SHEIKH, HUMERA N
Attorney Docket Number	065478-0159

	20	6183779		2001-02-06	Ouali et al.	
	21	6365184		2002-04-02	Depui et al.	
	22	6392525		2002-05-21	Kato et al.	
	23	6613354		2003-09-02	Depui et al.	
	24	6759935		2004-07-06	Moro et al.	
	25	5464632		1995-11-07	Cousin et al.	
	26	5731002		1998-03-24	Olovson et al.	
	27	6299904		2001-10-09	Shimizu et al.	
	28	6328994		2001-12-11	Shimizu et al.	
	29	6183776		2001-02-06	Depui et al.	
	30	5589491		2007-10-18	Nakanishi et al.	

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Not for submission under 37 CFR 1.99)

Application Number		09955801
Filing Date		2001-09-19
First Named Inventor	Taneja, Rajneesh	
Art Unit	1615	
Examiner Name	SHEIKH, HUMERA N	
Attorney Docket Number	065478-0159	

	31	6096340		2000-08-10	Chih-Ming Chen et al.	
	32	5750104		1998-05-12	Sipos	
	33	6328993		2001-12-11	Linder et al.	
	34	5312818		1994-05-17	Rubin et al.	
	35	6013281		2000-01-11	Lundberg	
	36	6258845		2001-07-01	Gerner	
	37	5952021		1999-09-14	Santus	
	38	6800307		2004-10-05	Matthews et al.	

If you wish to add additional U.S. Patent citation information please click the Add button.

U.S.PATENT APPLICATION PUBLICATIONS

Examiner Initial*	Cite No	Publication Number	Kind Code ¹	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear
	1	20020051814		2002-05-02	Chen	

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number	09955801
Filing Date	2001-09-19
First Named Inventor	Taneja, Rajneesh
Art Unit	1615
Examiner Name	SHEIKH, HUMERA N
Attorney Docket Number	065478-0159

2	20020051814	2002-05-02	Chen
3	20020192299	2002-12-19	Taneja et al.
4	20020045646	2002-04-18	Phillips

If you wish to add additional U.S. Published Application citation information please click the Add button.

FOREIGN PATENT DOCUMENTS

Examiner Initial*	Cite No	Foreign Document Number ³	Country Code ²	Kind Code ⁴	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear	T ⁵
	1	85/03443	WO		1985-08-15	Sunshine et al.		<input type="checkbox"/>
	2	93/12517	WO		1993-06-24	Fujushita et al.		<input type="checkbox"/>
	3	95/32957	WO		1995-12-07	Von Unge		<input type="checkbox"/>
	4	96/01623	WO		1996-01-25	Bergstrand et al.		<input type="checkbox"/>
	5	96/01625	WO		1996-01-25	Bergstrand et al.		<input type="checkbox"/>
	6	96/07421	WO		1996-03-14	Satoh		<input type="checkbox"/>

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number		09955801	
	Filing Date		2001-09-19	
	First Named Inventor	Taneja, Rajneesh		
	Art Unit	1615		
	Examiner Name	SHEIKH, HUMERA N		
	Attorney Docket Number	065478-0159		

U.S.PATENTS

Examiner Initial*	Cite No	Patent Number	Kind Code ¹	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear
	1					

If you wish to add additional U.S. Patent citation information please click the Add button.

U.S.PATENT APPLICATION PUBLICATIONS

Examiner Initial*	Cite No	Publication Number	Kind Code ¹	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear
	1					

If you wish to add additional U.S. Published Application citation information please click the Add button.

FOREIGN PATENT DOCUMENTS

Examiner Initial*	Cite No	Foreign Document Number ³	Country Code ² i	Kind Code ⁴	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear	T ⁵
	1	58056664	JP		1983-04-04			<input type="checkbox"/>
	2	01/51050	WO		2001-07-19	University of Missouri		<input type="checkbox"/>
	3	2358136	GB		2001-07-18	DeMontfort Univ.		<input type="checkbox"/>

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number		09955801
Filing Date		2001-09-19
First Named Inventor	Taneja, Rajneesh	
Art Unit	1615	
Examiner Name	SHEIKH, HUMERA N	
Attorney Docket Number	065478-0159	

	7	96/22780	WO		1996-08-01	Lichtenberger et al.		<input type="checkbox"/>
	8	96/24375	WO		1996-08-15	Depui et al.		<input type="checkbox"/>
	9	97/25064	WO		1997-07-17	Depui et al.		<input type="checkbox"/>
	10	97/25066	WO		1997-07-17	Depui et al.		<input type="checkbox"/>
	11	98/11879	WO		1998-03-26	Shell et al.		<input type="checkbox"/>
	12	98/13073	WO		1998-04-02	Lichtenberger et al.		<input type="checkbox"/>
	13	98/50033	WO		1998-11-12	Lundy et al.		<input type="checkbox"/>
	14	99/01000	WO		1999-01-07	Jokinen		<input type="checkbox"/>
	15	99/12524	WO		1999-03-18	Skinhoh et al.		<input type="checkbox"/>
	16	99/36060	WO		1999-07-22	Wilson et al.		<input type="checkbox"/>
	17	99/39700	WO		1999-08-12	Esposito et al.		<input type="checkbox"/>

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	09955801
Filing Date	2001-09-19
First Named Inventor	Taneja, Rajneesh
Art Unit	1615
Examiner Name	SHEIKH, HUMERA N
Attorney Docket Number	065478-0159

18	99/59612	WO		1999-11-25	Gevas et al.		<input type="checkbox"/>
19	99/66919	WO		1999-12-29	Ohannesian et al.		<input type="checkbox"/>
20	00/16750	WO		2000-03-30	Pettersson et al.		<input type="checkbox"/>
21	00/27366	WO		2000-05-18	Bergstrand et al.		<input type="checkbox"/>
22	00/50007	WO		2000-08-31	Patel et al.		<input type="checkbox"/>
23	00/50037	WO		2000-08-31	Garvey et al.		<input type="checkbox"/>
24	00/51583	WO		2000-09-08	Rubin et al.		<input type="checkbox"/>
25	00/69438	WO		2000-11-23	Rumsey et al.		<input type="checkbox"/>
26	00/71122	WO		2000-11-30	Malcolm		<input type="checkbox"/>
27	00/72838	WO		2000-12-07	Eek et al.		<input type="checkbox"/>
28	01/03707	WO		2000-12-14	Mandel et al.		<input type="checkbox"/>

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number		09955801
Filing Date		2001-09-19
First Named Inventor	Taneja, Rajneesh	
Art Unit	1615	
Examiner Name	SHEIKH, HUMERA N	
Attorney Docket Number	065478-0159	

29	01/13897	WO		2001-01-18	Wilson et al.		<input type="checkbox"/>
30	01/16750	WO		2001-03-08	West et al.		<input type="checkbox"/>
31	01/19330	WO		2001-03-22	DeBony et al.		<input type="checkbox"/>
32	01/37808	WO		2001-05-31	Patel et al.		<input type="checkbox"/>
33	4432262	DE		1995-07-20	Denecke		<input type="checkbox"/>
34	0426479	EP		1994-02-16	Goldman et al.		<input type="checkbox"/>
35	2105193	GB		1983-03-23	Marriott et al.		<input type="checkbox"/>
36	2105588	GB		1983-03-30	Brittain et al.		<input type="checkbox"/>
37	2120938	GB		1983-12-14	Ezer et al.		<input type="checkbox"/>
38	P2000-26296	JP					<input type="checkbox"/>
39	00/51584	WO		2000-09-08	Rubin et al.		<input type="checkbox"/>

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number		09955801
Filing Date		2001-09-19
First Named Inventor	Taneja, Rajneesh	
Art Unit	1615	
Examiner Name	SHEIKH, HUMERA N	
Attorney Docket Number	065478-0159	

40	94/25070	WO		1994-11-10	Astra Aktiebolag		<input type="checkbox"/>
41	00/74654	WO		2000-05-31	Byk Gulden		<input type="checkbox"/>
42	02/45692	WO		2001-05-12	Byk Gulden		<input type="checkbox"/>
43	02/22108	WO		2002-03-21	Chih Ming Chen		<input type="checkbox"/>
44	19925710	DE		2000-12-14	Gulden et al.		<input type="checkbox"/>
45	0547000	EP		1993-06-16			<input type="checkbox"/>
46	745493	GB		2007-10-18	MacLeans Ltd.		<input type="checkbox"/>
47	94/02140	WO		1994-02-03	Yoshito Mi Pharmaceutical Industries, Ltd.		<input type="checkbox"/>
48	97/25030	WO		1997-07-17	Astra Aktiebolag		<input type="checkbox"/>
49	11-110462	JP		2007-10-18	Eisai Co. Ltd.		<input type="checkbox"/>
50	05-194229	JP		1993-03-08	Kangefu Chem. Ind. Co. Ltd.		<input type="checkbox"/>

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number		09955801
	Filing Date		2001-09-19
	First Named Inventor	Taneja, Rajneesh	
	Art Unit	1615	
	Examiner Name	SHEIKH, HUMERA N	
	Attorney Docket Number	065478-0159	

If you wish to add additional Foreign Patent Document citation information please click the Add button

NON-PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T ⁵
	1	File history of EP Patent Application No: 0426479B1 including the following: European patent application as filed, European search report of February 22, 1991, First Office Action of August 10, 1992 and applicant's reply of December 3, 1992, Communication under Rule 51(4) EPC of February 17, 1993, Applicant's letter of July 30, 1993, Decision to grant a European patent pursuant to Article 97(2) EPC of January 6, 1994 including the non-patent references cited, Communication of notices of opposition (Rule 57(1) EPC) of December 22, 1994, Communication of	<input type="checkbox"/>
	2	Search Results for NSAIDS in Combination with Proton Pump Inhibitors-performed in 2001	<input type="checkbox"/>
	3	Search Results for Proton Pump Inhibitors and NSAIDS co-administered - performed in 2001	<input type="checkbox"/>
	4	WILSON INGALILL ET AL.: "Management of gastroduodenal ulcers and gastrointestinal symptoms associated with nonsteroidal anti-inflammatory drug therapy: A summary of four comparative trials with omeprazole, ranitidine, misoprostol and placebo" Current Therapeutic Research, December, 2001, pp. 835-850, Vol. 62, No. 12	<input type="checkbox"/>
	5	PHILLIPS, JEFFREY O. ET AL., "A Prospective Study of Simplified Omeprazole Suspension for the Prophylaxis of Stree-Related Mucosal Damage," Crit. Care Med., 1996, pp. 1793-1800, Vol. 24 No. 11	<input type="checkbox"/>
	6	LANDES, B. DELHOTAL ET AL., "Clinical Pharmacokinetics of Lansoprazole," Clin. Pharmacokinet., 1995, pp. 458-470, Vol. 28, No. 6	<input type="checkbox"/>
	7	SHARMA, V.K. ET AL., "The Effects on Intragastric Acidity of Per-Gastrostomy Administration of an Alkaline Suspension of Omeprazole," Aliment. Pharmacol. Ther., 1999, pp. 1091-1095, Vol. 13	<input type="checkbox"/>
	8	SHARMA, V.K. ET AL., "Oral pharmacokinetics of Omeprazole and Lansoprazole After Single and Repeated Doses as Intact Capsules or as Suspensions in Bicarbonate," Aliment. Pharmacol. Ther., 2000, pp. 887-892, Vol. 14, No. 7	<input type="checkbox"/>
	9	SHARMA, V.K. ET AL., "Simplified Lansoprazole Suspension - A Liquid Formulation of Lansoprazole Effectively Suppresses Intragastric Acidity When Administered Through a Gastrostomy" Am. J. Gastroenterology, August 1999, pp. 1813-1817, Vol. 94, No. 7	<input type="checkbox"/>

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number		09955801
	Filing Date		2001-09-19
	First Named Inventor	Taneja, Rajneesh	
	Art Unit	1615	
	Examiner Name	SHEIKH, HUMERA N	
	Attorney Docket Number	065478-0159	

10	LEWIS, ET AL., "The Physical and Chemical Stability of Suspensions of Sustained-Release Diclofenac Microspheres" J. Microencapsulation, Sept. 1, 1998, pp. 555-567 Vol. 15, No. 5	<input type="checkbox"/>
11	SHARMA, V.K. ET AL., "The Pharmacodynamics of Lansoprazole Administered via Gastrostomy as Intact, Non-Encapsulated Granules," Aliment. Pharmacol. Ther., 1998, pp. 1171-1174, Vol. 12,	<input type="checkbox"/>
12	SHARMA, V.K., "Comparison of 24-hour Intragastric pH Using Four Liquid Formulations of Lansoprazole and Omeprazole," Am. J. Health Syst. Pharm., Dec. 1, 1999, Vol. 56 Supp. 4.	<input type="checkbox"/>

If you wish to add additional non-patent literature document citation information please click the Add button

EXAMINER SIGNATURE

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. ² Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). ³ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁴ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁵ Applicant is to place a check mark here if English language translation is attached.